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Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)			
9					
Office Action Summary	10/761,846	DESHMUKH, A. JAY			
omec Action Gummary	Examiner	Art Unit			
The MAIL INC DATE of this communication of	Leon Y Lum	1641			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a n  - If NO period for reply is specified above, the maximum statutory perion  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the main earned patent term adjustment. See 37 CFR 1.704(b).	N. 1.136(a). In no event, however, may a reply be timely within the statutory minimum of thirty (30) dayed will apply and will expire SIX (6) MONTHS from tute, cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
<ol> <li>Responsive to communication(s) filed on <u>04 June 2004</u>.</li> <li>This action is FINAL. 2b) ☐ This action is non-final.</li> <li>Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11, 453 O.G. 213.</li> </ol>					
Disposition of Claims					
<ul> <li>4)  Claim(s) 1-12 is/are pending in the application.</li> <li>4a) Of the above claim(s) 12 is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-11 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
<ul> <li>9) The specification is objected to by the Examination The drawing(s) filed on 20 January 2004 is/an Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction.</li> <li>11) The oath or declaration is objected to by the</li> </ul>	re: a) $\square$ accepted or b) $\boxtimes$ objected ne drawing(s) be held in abeyance. See ection is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date 29 April 2004.	4) Interview Summary Paper No(s)/Mail Da 08) 5) Notice of Informal P 6) Other:				

#### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-11, drawn to an automated microfluidic system, classified in class 422, subclass 50.
  - II. Claim 12, drawn to a method of detecting a protein, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can practice the materially different process of liquid deposition by dispensing fluid in the reservoirs through the outlets via the compressed-air storage tank.
- 3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination

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purposes as indicated is proper. Group I is a device that requires searching for hydrophobic barriers, which is not a search required for Group II. Group II is a method

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that requires searching for steps to induce antigen-antibody reactions, which is not a

search required for Group I.

4. During a telephone conversation with Sonja Bae on 13 January 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-11. Affirmation of this election must be made by applicant in replying to this Office action. Claim 12 is withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

### Priority

#### Information Disclosure Statement

5. With respect to documents 2002-0043553 and 2002-0071853 listed in the Information Disclosure Statement filed 29 April 2004, only the abstracts have been considered since English translations of the full text documents have not been provided.

#### **Drawings**

6. The drawings are objected to because it is difficult to distinguish between embodiments in Figures 1-5 due to poor quality. For example, Figures 1-2 indicate embodiments 1-5 and 10. However, due to the extremely dark background of device 10, it is not possible to determine where references 1-5 are located since the arrows blend in with the background of device 10. With respect to Figures 3-4, it is not possible to determine which reservoirs are sample, dye, or control since the legend indicates the reservoirs as shades of gray that cannot be distinguished in the Figures. In addition, Figure 5 is extremely dark and it is difficult to distinguish individual components of the drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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## Claim Rejections - 35 USC § 112

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- 7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
  - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 8. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 9. In claim 1, line 4, the phrase "various concentrations" is vague and indefinite.

  The specification does not provide a definition for the phrase and it is unclear as to what types of concentrations are being claimed.
- 10. In claim 1, lines 5-7, the phrase "each of the sample reservoir, the dye reservoir, and the control reservoirs having a hydrophobic upper barrier connected to a compressed-air inlet and a hydrophobic lower barrier connected to a liquid outlet" is vague and indefinite. It is unclear whether the sample reservoir, dye reservoir, and control reservoirs each have hydrophobic upper barriers and lower barriers that connect to the same inlet and outlet, or to separate inlets and outlets.
- 11. In claim 1, line 10, the term "that" is vague and confusing. The term doesn't seem to fit in the context of the sentence.

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12. In claim 1, lines 11-13, the phrase "an outlet, and antibodies immobilized on an

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inner surface, the dye/buffer inlet part having a dye inlet connected to a liquid outlet of

the dye reservoir and a buffer inlet port" is vague and indefinite. It is unclear whether

the instant phrase refers embodiments that are in each of the "sample detection part

and the control detection parts" (lines 9-10), or whether the instant phrase refers to

embodiments that are part of the microfluidic channel (line 8), but not part of the sample

detection part and the control detection parts.

13. In claim 1, lines 12-13, the phrase "the dye/buffer inlet part having a dye inlet

connected to a liquid outlet of the dye reservoir and a buffer inlet port" is vague and

indefinite. It is unclear whether the dye inlet is connected to both the liquid outlet and

the buffer inlet port, or just the liquid outlet.

14. In claim 1, line 16, the phrase "the buffer inlet ports" is vague and confusing.

Line 13 of the instant claim recites "a buffer inlet port". It is therefore unclear and

confusing as to whether the claimed invention has one or multiple buffer inlet ports.

15. In claim 6, it is unclear whether the claimed limitation refers to a pump that

connects the compressed-air storage tank to the buffer storage tank, a single pump that

is connected to both the compressed-air storage tank and the buffer storage tank, one

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pump that connects to the compressed-air storage tank and another pump that

connects to the buffer storage tank, or another limitation.

16. In claim 10, lines 2-4, the phrase "are three-way valves that are closed to allow

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external air to flow into the compressed-air inlet ports and are opened toward the

compressed-air storage tank" is vague and confusing. The phrase seems to claim that

the three-way valves are both opened and closed that the same time, and it is unclear

as to which limitation is claimed.

17. Claim 1 recites the limitation "the protein of interest" in line 5. There is

insufficient antecedent basis for this limitation in the claim.

18. Claim 1 recites the limitation "the compressed air-inlets of the sample reservoir,

the dye reservoirs, and the control reservoirs" in lines 14-15. There is insufficient

antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

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20. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.

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- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 21. Claims 1-2 and 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfost et al (US 6,485,690 B1) in view of O'Connor et al (US 6,729,352 B2), Friedman et al (US 5,834,222), Griffin et al (US 5,321,123), and Courtright (US 4,598,628).

In the instant claims, Pfost et al reference teaches a reservoir layer 12 (i.e. cartridge reservoir part) and distribution 14 and well plate 16 layers (i.e. cartridge with a microfluidic channel), wherein the reservoirs are filled with a plurality of reagents (i.e. dye) or other materials, and wherein the plate includes a plurality of submicrotiter reaction wells (i.e. detection parts) with a plurality of drain feeds (i.e. outlet). See column 2, line 35 to column 3, line 11; and column 5, line 57 to column 6, line 31; and Figure 9. Pfost et al reference also teaches that in a five-layered processor, the top layer contains multi-welled reservoirs which convey the liquid contained in each of the wells to be pumped into the next layer one or more wells at a time (i.e. reservoirs containing solutions), and that the second layer has a plurality of microchannels that convey samples to appropriate sites on the next level. See column 10, line 48 to

column 11, line 19; and Figure 5. Pfost et al reference also teaches different apertures corresponding to reservoirs can be used to hold different materials. See column 13. lines 10-16. Pfost et al reference also teaches that fluids can also be delivered through tube 68 (i.e. dye/buffer inlet part having a dye inlet connected to a liquid outlet of a reservoir and a buffer inlet port), which enters the processor through the middle layer 64, or distribution layer, and deposited in the reaction wells in the bottom plate 66, or well plate layer. See column 9, lines 55-66 and Figure 23. Pfost et al reference also teaches that an external reservoir that distributes fluid into the process or is a buffer reservoir (i.e. buffer storage tank). See column 21, line 56 to column 22, line 13; and Figure 53. Pfost et al reference also teaches that any of the layers in the processor can incorporate optical elements (i.e. reader) with mechanism of detection (i.e. measures the degrees of reactions). See column 11, lines 41-49. Pfost et al reference also teaches a pressure pumping system (i.e. compressed-air storage tank connected to the compressed-air inlets of the reservoirs) to assist in loading and distributing reagents within the layers by transmitting pressurized air (i.e. compressed air). See column 6, lines 47-59; and Figure 9. Pfost et al reference also teaches that the lower well plate has a plurality of wells that are used to hold reagents or other materials in order for them to react to create products. See column 6, lines 13-16. Pfost et al reference also teaches that the processor can be used in immunology diagnostics. See column 5, lines 1-11, especially line 11.

However, Pfost et al reference fails to teach that the reservoir layer includes a sample reservoir, a dye reservoir, and a plurality of control reservoirs, each of the

sample reservoir, dye reservoir, and control reservoirs having a hydrophobic upper barrier connected to a compressed-air inlet and a hydrophobic lower barrier connected to a liquid outlet. Pfost et al reference also fails to teach antibodies immobilized on an inner surface and that the reader measures the degrees of antigen-antibody reactions in the sample and control detection parts based on variations in dye color. In addition, Pfost et al reference fails to teach valves connecting the compressed-air storage tank to the inlets of the reservoirs, and fails to teach valves connecting the buffer storage tank to the buffer inlet ports.

O'Connor et al reference teaches a chamber 314 enclosed by two hydrophobic porous membranes 303 and 305 on either side of the chamber, wherein membrane 303 is gas permeable/fluid impermeable and membrane 305 allows fluid flow therethrough only when the fluid is exposed to a vacuum after fluid metering, in order to provide membranes that allow selective vacuum-induced fluid flow through only one side of a chamber. See column 26, lines 21-41 and Figure 16B. Regarding the term "selective" in the statement above, Since O'Connor et al reference teaches that fluid flows through membrane 305 only after fluid metering, the initiation of vacuum-induced fluid flow is thereby considered to be "selective".

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Pfost et al with a chamber 314 enclosed by two hydrophobic porous membranes 303 (i.e. hydrophobic upper barrier) and 305 (i.e. hydrophobic lower barrier) on either side of the chamber, wherein membrane 303 is gas permeable/fluid impermeable and membrane 305 allows fluid flow therethrough only

when the fluid is exposed to a vacuum after fluid metering, as taught by O'Connor et al, in order to provide membranes that allow selective vacuum-induced fluid flow through only one side of a chamber. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including the dual hydrophobic membranes, as taught by O'Connor et al, in the device of Pfost et al, since Pfost et al teach flow of fluid from reservoirs into microchannels using pressurized air to move the fluid only in one direction, and the dual membranes taught by O'Connor et al would allow the selective movement of fluid from the reservoirs using pressurized air.

Friedman et al reference teaches an immunoassay with multiple standards as varying concentrations (i.e. control solutions of various concentrations), in order to allow one to perform a quantitative assay by comparison to the signals produced by the samples on a concentration vs. signal plot, wherein the signal is produced by a reaction with an enzyme conjugate/antibody complex that produces a detectable signal using a chromogen (i.e. dye color). See column 10, lines 39-57 and column 16, lines 54-67. Although Friedman et al reference does not explicitly teach a reader that measures antigen-antibody reactions, since the reference teaches detection of signals from immunoassays, it is necessarily required that the signals are detected by a reader that can detect antigen-antibody reactions.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Pfost et al with an immunoassay with multiple standards as varying concentrations (i.e. control solutions of various concentrations), as taught by Friedman et al, in order to allow one to perform a quantitative assay by

comparison to the signals produced by the samples on a concentration vs. signal plot.

One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including multiple standards, as taught by Friedman et al, in the device of Pfost et al, since Pfost et al teach immunoassays, and the multiple standards taught by Friedman et al is also applied to immunoassays.

Griffin et al reference teaches immobilized antibody molecules on a solid support, in order to provide a substrate for purification wherein the solid support is washed or rinsed with buffers formulated to remove macromolecules surrounding the support that are not specifically immunoreacted with the immobilized antibody molecules. See column 32, lines 17-36.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Pfost et al with immobilized antibody molecules on a solid support, as taught by Griffin et al, in order to provide a substrate for purification wherein the solid support is washed or rinsed with buffers formulated to remove macromolecules surrounding the support that are not specifically immunoreacted with the immobilized antibody molecules. One ordinary skill in the art at the time of the invention would have reasonable expectation of success in including immobilized antibodies, as taught by Griffin et al, in the device of Pfost et al, since Pfost et al teach immunoassays and that the reaction wells can contain materials that create products, and immobilized antibodies are one type of material that can create products and are used in immunoassays.

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Courtright reference teaches a switching valve, in order to provide selective expulsion of fluid under pressure from a tank as desired. See column 4, lines 44-49.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Pfost et al with a switching valve, as taught by Courtright, in order to provide selective expulsion of fluid under pressure from a tank as desired. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including a switching valve, as taught by Courtright, in the device of Pfost et al, since Pfost et al teach the flow of pressurized air and the flow of buffer from external fluid storage units, and the expulsion of fluid taught by Courtright is also performed under pressure from a storage unit.

With regards to claim 2, O'Connor et al reference teaches that membrane 303 is gas permeable/fluid impermeable and that fluid flows through membrane 305 only after an applied vacuum (i.e. allow only air to pass, not fluid, in an atmospheric pressure), as stated above. Since fluid will flow only when exposed to a vacuum, it is inherent that in the absence of a vacuum, liquid will not pass either membrane in atmospheric pressure.

With regards to claim 5, O'Connor et al reference teaches that the substrate layers can be formed from polytetrafluoroetyhylene. See column 8, lines 7-14. Since membranes 303 and 305 are considered substrate layers, as stated above, the membranes are formed from polytetrafluoroetyhylene.

With regards to claim 6, Pfost et al reference teaches pumping mechanisms 40 and 42 attached to pressure members 44 and 46, and a pump attached to an external reservoir. See column 6, lines 47-59; column 22, lines 33-41; and Figures 9 and 53.

With regards to claim 7, Pfost et al reference teaches that the well plate 16 is a standard well plate. See column 9, lines 5-14. Since the reaction wells (i.e. detection parts) are in a standard well plate, then all of the reaction wells (i.e. sample detection part and control detection part) have the same volume.

With regards to claims 8-9, since Pfost et al teaches that reservoirs can hold different reagents and materials, as stated above (see column 13, lines 10-16), one of the reservoirs has the capability of holding a reagent (i.e. dye) for immunoassays, and one of the reservoirs has the capability of holding a sample, both of the reagents and sample being taught by Pfost et al (see column 5, lines 1-11, especially line 11). In addition, a separate set of reservoirs has the capability of holding control samples, as taught by Friedman et al, as stated above. In addition, the path between each reservoir and their respective reaction well is the same distance, as depicted by the Figures stated above in Pfost et al reference. Therefore, with respect to claim 8, the distance (i.e. a portion) between the inlet of the part of the microfluidic channel in the second layer corresponding to a reservoir with reagent (i.e. dye inlet) and the outlet of a reaction well corresponding to a sample reservoir (i.e. outlet of the sample detection part) and the distance (i.e. a portion) between the inlet of the part of the microfluidic channel in the second layer corresponding to a reservoir with reagent (i.e. dye inlet) and the outlet of a reaction well corresponding to a control reservoir (i.e. outlet of one of the control detection parts) would invariably contain sections that overlap in distance (i.e. equal length). In addition, with respect to claim 9, the distance (i.e. a portion) between the inlet of tube 68 (i.e. buffer inlet port) and the outlet of a reaction well corresponding

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to a sample reservoir (i.e. outlet of the sample detection part) and the distance (i.e. a portion) between the inlet of tube 68 (i.e. buffer inlet port) and the outlet of a reaction well corresponding to a control reservoir (i.e. outlet of one of the control detection parts) would invariably contain sections that overlap in distance (i.e. equal length).

22. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfost et al (US 6,485,690 B1) in view of O'Connor et al (US 6,729,352 B2), Friedman et al (US 5,834,222), Griffin et al (US 5,321,123), and Courtright (US 4,598,628) as applied to claim 1 above, and further in view of Roe et al (US 6,093,869).

O'Connor et al, Friedman et al, Griffin et al, and Courtright references have been disclosed above, and O'Connor et al reference additionally teaches that layer 305 is more porous than layer 303. See column 26, lines 35-38. However, O'Connor t al, Friedman et al, Griffin et al, and Courtright references fail to teach that the lower hydrophobic barrier has a larger average pore size than the upper hydrophobic barrier.

Roe et al reference teaches two regions with different pore sizes, wherein a port regions has smaller pores than an inner region, in order to provide a permeability of the inner region that is relatively high compared to the permeability of the port region. See column 15, lines 39-47.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of O'Connor et al, Friedman et al, Griffin et al, and Courtright with two regions with different pore sizes, wherein a port regions has smaller pores than an inner region, as taught by Roe et al, in order to provide a permeability of

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the inner region that is relatively high compared to the permeability of the port region.

One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including membranes with two different pore sizes, as taught by Roe et al, in the device of O'Connor et al, Friedman et al, Griffin et al, and Courtright, since O'Connor et al, Friedman et al, Griffin et al, and Courtright teach a region enclosed by two membranes with different liquid permeabilities, and the membranes of Roe et al also provide different liquid permeabilities.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfost et al (US 6,485,690 B1) in view of O'Connor et al (US 6,729,352 B2), Friedman et al (US 5,834,222), Griffin et al (US 5,321,123), and Courtright (US 4,598,628) as applied to claim 1 above, and further in view of Roe et al (US 6,093,869) as applied to claim 3 above, and further in view of Oberhardt (US 5,601,991) and Ngo et al (US 5,219,529).

O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al references have been disclosed above, but fail to teach that the upper hydrophobic barrier has an average pore diameter that ranges from 0.2  $\mu$ m to 1  $\mu$ m and that the lower hydrophobic barrier has an average pore diameter that ranges from 2  $\mu$ m to 20  $\mu$ m.

Oberhardt reference teaches hydrophobic membranes with a pore size from 0.02 to 0.06 micron, in order to provide membranes that are gas impermeable but liquid impermeable that can use vacuum or pressure methods. See column 6, line 66 to column 7, line 7.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al with hydrophobic membranes with a pore size from 0.02 to 0.06 micron, as taught by Oberhardt, in order to provide membranes that are gas impermeable but liquid impermeable that can use vacuum or pressure methods. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including hydrophobic membranes with a pore size from 0.02 to 0.06 micron, as taught by Oberhardt, in the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al since O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al teach a hydrophobic membrane that is permeable only to gas under a vacuum, and the membrane of Oberhardt is also hydrophobic and can function under a vacuum.

Ngo et al reference teaches a polytetrafluoroethylene material with a porosity of about 5 microns, in order to provide a material which is permeable to the flow of liquids. See column 3, line 55 to column 4, line 27.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al with a polytetrafluoroethylene material with a porosity of about 5 microns, as taught by Ngo et al, in order to provide a material which is permeable to the flow of liquids. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including a polytetrafluoroethylene material with a porosity of about 5 microns, as taught by Ngo et al, in the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al since O'Connor et al, Friedman et

al, Griffin et al, Courtright, and Roe et al teach a polytetrafluoroethylene layer that is permeable to liquid, and the material of Ngo et al is also polytetrafluoroethylene and is permeable to liquids.

23. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfost et al (US 6,485,690 B1) in view of O'Connor et al (US 6,729,352 B2), Friedman et al (US 5,834,222), Griffin et al (US 5,321,123), and Courtright (US 4,598,628) as applied to claim 1 above, and further in view of Knedlik (US 4,381,099).

O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al references have been disclosed above, but fail to disclose that the valves that connect the compressed-air inlets and the compressed-air storage tank are three-way valves that are closed to allow external air to flow into the compressed-air inlet ports and are opened toward the compressed-air storage tank.

Knedlik reference teaches a three way valve that connects a control line with a source of fluid pressure and a fluid pressure exhaust, wherein the fluid pressure is compressed air and the pressure exhaust is a vent to atmosphere, in order to provide selective alternation between the compressed air and vent to atmosphere. See column 4, lines 28-41 and Figures 1-2.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al with a three way valve that connects a control line with a source of fluid pressure and a fluid pressure exhaust, wherein the fluid pressure is compressed air and

the pressure exhaust is a vent to atmosphere, as taught by Knedlik, in order to provide selective alternation between the compressed air and vent to atmosphere. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a three way valve, as taught by Knedlik, in the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al, since O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al teach valves that regulate the flow of compressed air, and the three way valve taught by Knedlik is also capable of regulating compressed air.

24. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pfost et al (US 6,485,690 B1) in view of O'Connor et al (US 6,729,352 B2), Friedman et al (US 5,834,222), Griffin et al (US 5,321,123), and Courtright (US 4,598,628) as applied to claim 1 above, and further in view of DeCarbo, Sr. et al (US 5,697,132).

O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al references have been disclosed above, but fail to disclose a controller that controls the opening and closing of the outlets of the sample detection part and the control detection parts.

DeCarbo, Sr. et al reference teaches a controller, in order to selectively control the flow of fluids through fluid supply conduits and outlet ports. See column 8, lines 44-61.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al with a controller, as taught by DeCarbo, Sr. et al, in order to selectively

control the flow of fluids through fluid supply conduits. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including a three way valve, as taught by DeCarbo, Sr. et al, in the device of O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al, since O'Connor et al, Friedman et al, Griffin et al, Courtright, and Roe et al teach flow of fluids through an outlet, and the controller taught by DeCarbo, Sr. et al is capable of regulating the flow of fluids through outlet ports.

#### Conclusion

- 25. No claims are allowed.
- 26. The prior art made of reference and not relied upon is considered pertinent to Applicant's disclosure:

Root et al (US 4,895,706) teaches a linear array of wells having top and bottom ends with filters and using a vacuum manifold.

Balch (US 6,083,763) teaches an apparatus with a plurality of test sites and delivery of fluids from a storage vessel with an array of wells.

Demer (US 6,117,396) teaches a liquid dispensing device comprising a reagent fill channel, one or more metering capillaries connected to the reagent fill channel and having an exit, and one or more sources of gas connected to the reagent fill channel.

Mikulsky (US 6,146,595) teaches a system with a plurality of sample vials, each vial having an inlet and outlet, the inlets and outlets connecting to gas manifolds for distributing gas and collection.

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McBride (US 6,395,232 B1) teaches a microfluidic delivery system having fluid input, fluid reservoirs, and a gas delivery system.

Brennan (US 2003/0069411 A1) teaches an apparatus with an array of nozzles, each nozzle coupled to a reservoir, and a base assembly having an array of reaction wells with nozzles for deposition of liquid reagent into selected reagent wells.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Leon Y Lum
Patent Examiner

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